

### REMARKS

Claims 1, 3-10, 15-51, 63 and 68-77 are currently pending.

Applicants thank the Examiner for withdrawing the previous rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112.

### ELECTION/RESTRICTIONS

Claims 37 and 38 have been withdrawn. Applicants however, request the rejoinder of claims 37-38 if the pending claims are found allowable.

### CLAIM REJECTIONS

#### *Rejection under 35 U.S.C. § 103*

##### *Bicchi, Yang, Pol and Karatzas*

The Examiner has rejected claims 1, 3-10, 15-36, 39-40, 50-51, 63 and 69-77 under 35 U.S.C. § 103(a) as being unpatentable over Bicchi et al. (*Phytochemical Analysis*, 11, 236-242 (2000)) ("Bicchi"), Yang et al., (*Bioorganic & Medicinal Chemistry*, 9, 347-36 (2001)) ("Yang"), Pol et al., (*Letters in Applied Microbiology*, 29, 166-170 (1999)) ("Pol"), and Karatzas et al., (*J. Applied Microbiology*, 89, 296-301 (2000)) ("Karatzas"). See Office Action at p. 3.

Claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1. Claims 70-77 depend from independent claim 69.

Claim 1 relates to a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Claim 69 relates to a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

While Bicchi discloses that rosemary extracts of phenolic diterpenes are antioxidants (see Office Action at p. 4), Bicchi makes no mention of nisin (an antimicrobial material), or its

combination with the phenolic diterpenes. This fact is acknowledged by the Examiner at p. 4 of the Office Action.

Pol discloses that the combination of nisin and either carvacrol or carvone results in synergy. See p. 168 of Pol. However, Pol makes absolutely no mention of phenolic diterpenes or their combination with nisin. Yang discloses that a number of diterpenes display anti-bacterial activities against MRSA and VRE. See p. 347 of Yang. However, Yang does not mention that such diterpenes should be combined with nisin. Karatzas discloses that carvone may act to reduce the viability of *Listeria monocytogenes*. See p. 296 of Karatzas. Further, it is also disclosed in Karatzas that the combination of carvone and heat treatment results in an effect on the viability of *Listeria monocytogenes*. See p. 299 of Karatzas. However, no mention or suggestion is made in Karatzas of nisin or its combination with phenolic diterpenes.

In summary, the above-mentioned references disclose that phenolic diterpenes are antioxidants, that diterpenes are antibacterial, that carvone in combination with mild heat treatment may have an effect on the viability of *Listeria monocytogenes* and that nisin and carvone or carvacrol may have an effect on the viability of *Listeria monocytogenes*. However, there is no teaching, suggestion or motivation to modify any of the above-mentioned references to arrive at the composition of the present claims.

By contrast, Applicants have surprisingly found in the present invention that the specific combination of

- i) an antimicrobial material, such as nisin, and
- ii) phenolic diterpenes in an amount of greater than 1 wt. % based on the composition, results in a synergistic effect on the viability of *Listeria monocytogenes* and *Bacillus cereus* compared to the antimicrobial properties of the two components alone.

This effect is supported by the data presented throughout the specification. For example, Table 5 (page 42 of the present application) shows a summary of results demonstrating the nisin/phenolic diterpene synergy against *Listeria* and *Bacillus* in pasteurized chicken soup. This is clear and unmistakable support for the synergistic combination of an antimicrobial material, such as nisin, and phenolic diterpenes at the specific concentration of the claims. This surprising result is clear from the presented data.

As acknowledged by the Examiner, none of the cited documents teach or suggest the specific combination of nisin and phenolic diterpenes. See Office Action at p. 5. However, the Examiner has alleged firstly, that the combination would be made because the components are used for the same purpose, and secondly, that the claimed amounts would obviously reached because they are mere routine optimization. See Office Action at p. 5-6. Applicants respectfully traverse this contention.

MPEP 2143(A) states that

[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combinations yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

This is clearly not the case here.

As shown by the data in the specification, the combination of nisin and phenolic diterpenes as claimed does not result in a mere additive effect. In fact, a synergistic effect is produced. See for example, Table 5 at p. 42 of the specification. The skilled person cannot be expected to arrive at a synergistic combination by mere routine optimization. On the contrary, the presence of synergy between two components is a surprising and unexpected effect which can not be considered as being obvious. Thus, even if the combination of the components would be obvious, which is certainly not the case here, the specific amount of the phenolic diterpene can not be considered to be obvious in view of the surprising synergy which is displayed.

As a further point, Applicants note that Pol discloses an effect between nisin and either carvacrol or carvone. See p. 168 of Pol. Neither of these two compounds are phenolic diterpenes. It is known in the art that carvone and carvacrol impart a strong flavor to a resulting composition or foodstuff and so their use in foodstuffs above the levels that the present composition would provide is considered as undesirable. As a result, the skilled person would have to choose between using these compounds for their positive effect on nisin and their negative effect on taste. Applicants' invention has, however, overcome this issue by providing a

de-odorized composition which is still capable of displaying a synergistic effect, i.e. between the antimicrobial and the phenolic diterpenes where the composition contains carvacrol in an amount of less than 0.075wt. % and carvone in an amount of less than 15wt. %.

Additionally, Karatzas describes the combination of carvone and heat treatment has an effect on the viability of *Listeria monocytogenes*. See p. 299 of Karatzas. A person of skill in the art would not be motivated to modify the teachings of Karatzas and omit the heat treatment from the composition. In fact, a person of skilled in the art would maintain the use of heat treatment and carvone.

These choices do not provide the skilled person with the motivation to arrive at the composition of claim 1. Indeed, the only motivation to do so comes from Applicants' discovery though use of hindsight. The Examiner's obviousness rejection of the subject matter of the claims violates the basic considerations of obviousness as set forth in MPEP 2141 ("[t]he references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention."). Accordingly, Applicants respectfully request that these rejections be reconsidered and withdrawn.

As such, Bicchi, Yang, Pol and Karatzas do not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiateae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Bicchi, Yang, Pol and Karatzas further do not teach or suggest a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

Accordingly, since claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1 and claims 70-77 depend from independent claim 69, those claims are patentable over Bicchi, Pol, Karatzas and Yang for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

***Bicchi, Yang, Pol, Karatzas and Bard***

The Examiner has rejected claims 1, 3-10, 15-36, 39-40, 50-51, 63 and 69-77 under 35 U.S.C. § 103(a) as being unpatentable over Bicchi, Yang, Pol, Karatzas and further in view of U.S. Patent No. 3,679,434 to Bard et al. (“Bard”). See Office Action at p. 6. Claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1. Claims 70-77 depend from independent claim 69.

As explained above, Bicchi, Yang, Pol and Karatzas do not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Bicchi, Yang, Pol and Karatzas do not teach or suggest a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

Bard does not remedy the deficiencies of the above-mentioned references. Bard “relates, generally, to innovations and improvements in preparing bodies, e.g. roasts, of whole cooked fresh meat of predetermined uniform size, shape and weight suitable for slicing, characterized by their resistance to the rancidity which normally develops in such bodies on cooling after cooking.” See col. 1, lines 33-38 of Bard. In particular, Bard describes “the novel step of injecting such primal cuts or chunks with a source of polyphosphate ions with the result that in the cooked bodies or roasts the polyphosphate ions are distributed substantially uniformly throughout the meat bodies and serve to prevent the cooked meat from becoming rancid on cooling.” See col. 1, lines 50-56 of Bard. Bard does not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Bard does not teach or suggest a foodstuff having a phenolic

diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

Accordingly, claims 1, 69 and claims that depend therefrom, are patentable over the combination of Bicchi, Yang, Pol, Karatzas and Bard for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

***Bicchi, Yang, Pol, Karatzas, Bard and Todd***

The Examiner has rejected claims 1, 3-10, 15-36, 39-40, 50-51, 63 and 69-77 under 35 U.S.C. § 103(a) as being unpatentable over Bicchi, Yang, Pol, Karatzas, Bard and further in view of U.S. Patent No. 5,084,923 to Todd Jr. ("Todd"). See Office Action at p. 9-10. Claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1. Claims 70-77 depend from independent claim 69.

As explained above, Bicchi, Yang, Pol, Karatzas and Bard do not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Bicchi, Yang, Pol, Karatzas and Bard do not teach or suggest a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

Todd does not remedy the deficiencies of the above-mentioned references. Todd teaches anti-oxidant compositions which includes activated ascorbic acid as an antioxidant. See Abstract of Todd. Todd does not describe or mention antimicrobial compositions. Todd does not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Todd does not teach or suggest a

foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

Accordingly, claims 1, 69 and claims that depend therefrom, are patentable over the combination of Bicchi, Yang, Pol, Karatzas, Bard and Todd for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

***Bicchi, Yang, Pol, Karatzas, Bard, Todd and King***

The Examiner has rejected claims 1, 3-10, 15-36, 39-40, 50-51, 63 and 69-77 under 35 U.S.C. § 103(a) as being unpatentable over Bicchi, Yang, Pol, Karatzas, Bard, Todd and further in view of U.S. Patent No. 6,451,365 to King et al. ("King"). See Office Action at p. 13. Claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1. Claims 70-77 depend from independent claim 69.

As explained above, Bicchi, Yang, Pol, Karatzas, Bard and Todd do not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition. Bicchi, Yang, Pol, Karatzas, Bard and Todd do not teach or suggest a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

King does not remedy the deficiencies of the above-mentioned references. King describes providing antimicrobial compositions that include nisin and hops acid extracts. See Abstract of King. As explained in the Response to Office Action filed on August 28, 2008, hops acids are chemically different from rosemary extracts and thus their method of action is also different. King does not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the *Labiatae* family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the

composition and carvone in an amount of less than 15 wt. % based on the composition. King does not teach or suggest a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g.

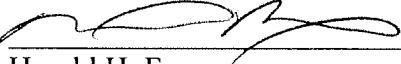
Accordingly, claims 1, 69 and claims that depend therefrom, are patentable over the combination of Bicchi, Yang, Pol, Karatzas, Bard, Todd and King for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

### **CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. A petition for extension of time is attached. Applicants believe that the claims now pending are in condition for allowance. Should any other fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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